

REMARKS

I. INTRODUCTION

Claims 142-146 were indicated as being allowed. Claims 68, 89, 113, 125, 131 and 142-147 have been amended. In particular, claims 68, 89, 113, 125 and 131 were amended herein above to clarify the subject matter recited therein. Claim 147 has been amended herein above to remove an issue related to indefiniteness raised by the Patent Trial and Appeal Board ("PTAB") in the Decision on Appeal dated November 28, 2012 regarding indefiniteness thereof, but not for any reasons relating to patentability thereof. Claims 142-146 have been amended to remove a recitation thereof so as to broaden respective scopes thereof. New claims 163-165 have been added.

Accordingly, claims 68, 70-72, 74, 76-82, 84-94, 96-102, 104-148, 150, 151, 153, 154, 156, 157 and 159-166 are now under consideration in the above-referenced application. Provided above, please find a claim listing indicating the amendments to claims 68, 89, 113, 125, 131 and 142-147, the addition of claims 163-165, and the status of other claims on separate sheets so as to comply with the requirements set forth in 37 C.F.R. § 1.121. It is respectfully submitted that no new matter has been added.

II. REJECTION OF CLAIM 147 UNDER 35 U.S.C. § 112 SHOULD BE WITHDRAWN

In the Decision, the PTAB newly rejected claim 147 under 35 U.S.C. § 112, second paragraph as being allegedly indefinite. The reason for this rejection was due to an apparent inconsistency in the language thereof, as discussed during an Oral Hearing of November 15, 2012 (the "Oral Hearing") for the present application. As the Examiner shall ascertain, claim 147 has been amended as suggested by Applicants' counsel during the

Hearing to remove any inconsistency therein. Accordingly, for at least such reason(s), the § 112, second paragraph rejection of claim 147 should be withdrawn.

III. REJECTIONS UNDER 35 U.S.C. §§ 102(b) AND 103(a) SHOULD BE WITHDRAWN

Claims 68-75, 81, 82, 84-87, 89-95, 101, 102, 104-107, 109-116, 118-128, 130, 137-140, 147-157, 161 and 162 stand finally rejected under 35 U.S.C. § 102(b) as being allegedly anticipated by U.S. Patent No. 5,318,024 issued to Kittrell et al. (the "Kittrell Patent"). Claims 88, 108, 117, 129, 131-136, 141 and 158-160 stand finally rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over the Kittrell Patent, in view of U.S. Patent No. 3,941,121 issued to Olinger et al. (the "Olinger Patent"). Claims 76-78 and 96-98 stand finally rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over the Kittrell Patent, in view of International Publication No. WO 99/44089 by Webb et al. (the "Webb Publication"). Claims 79, 80, 99 and 100 stand finally rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over the Kittrell Patent, in view of U.S. Patent No. 5,275,594 issued to Baker et al. (the "Baker Patent"). Applicants respectfully assert that the Kittrell Patent, taken alone or in combination with the Olinger Patent, the Webb Publication and/or the Baker Patent, fails to teach, suggest or disclose the subject matter recited in amended independent claims 68, 89, 113, 125 and 131 (which include the subject matter of now-cancelled claims 69, 73 and 75), and the claims which depend therefrom, for at least the following reasons.

In order for a claim to be rejected as anticipated under 35 U.S.C. § 102, each and every element as set forth in the claim must be found, either expressly or inherently described, in a single prior art reference. Manual of Patent Examining Procedures, §2131;

also see *Lindeman Maschinenfabrik v. Am Hoist and Derrick*, 730 F.2d 1452, 1458 (Fed. Cir. 1984).

Under 35 U.S.C. § 103(a), a person is not entitled to a patent even though the invention is not identically disclosed or described as set forth in §102, “if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.” 35 U.S.C. § 103(a).

The objective standard for determining obviousness under 35 U.S.C. § 103, as set forth in *Graham v. John Deere, Co.*, 383 U.S. 1 (1966), requires a factual determination to ascertain: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; and (3) the differences between the claimed subject matter and the prior art. Based on these factual inquiries, it must then be determined, as a matter of law, whether or not the claimed subject matter as a whole would have been obvious to one of ordinary skill in the art at the time the alleged invention was made. *Graham*, 383 U.S. at 17. Courts have held that there must be some suggestion, motivation or teaching of the desirability of making the combination claimed by the applicant (the “TSM test”). See *In re Beattie*, 974 F.2d 1309, 1311-12 (Fed. Cir. 1992). This suggestion or motivation may be derived from the prior art itself, including references or disclosures that are known to be of special interest or importance in the field, or from the nature of the problem to be solved. *Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568, 1573 (Fed. Cir. 1996).

Although the Supreme Court criticized the Federal Circuit’s application of the TSM test, see *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741, (2007) the Court also indicated that the TSM test is not inconsistent with the *Graham* analysis recited

in the *Graham v. John Deere* decision. *Id.*; see *In re Translogic Technology, Inc.*, No. 2006-1192, 2007 U.S. App. LEXIS 23969, *21 (October 12, 2007). Further, the Court underscored that “it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.” *KSR*, 127 S. Ct. at 1741. Under the precedent established in *KSR*, however, the presence or absence of a teaching, suggestion, or motivation to make the claimed invention is merely one factor that may be weighed during the obviousness determination. *Id.* Accordingly, the TSM test should be applied from the perspective of a person of ordinary skill in the art and not the patentee, but that person is creative and not an automaton, constrained by a rigid framework. *Id.* at 1742. However, “the reference[s] must be viewed without the benefit of hindsight afforded to the disclosure.” *In re Paulsen*, 30 F.3d 1475, 1482 (Fed. Cir. 1994).

The prior art cited in an obviousness determination should create a reasonable expectation, but not an absolute prediction, of success in producing the claimed invention. *In re O’Farrell*, 853 F.2d 894, 903-04 (Fed. Cir. 1988). Both the suggestion and the expectation of success must be in the prior art, not in applicant’s disclosure. *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.*, 927 F.2d 1200, 1207 (Fed. Cir. 1991) (citing *In re Dow Chem. Co.*, 837 F.2d 469, 473 (Fed. Cir. 1988)). Further, the implicit and inherent teachings of a prior art reference may be considered under a Section 103 analysis. See *In re Napier*, 55 F.3d 610, 613 (Fed. Cir. 1995).

Secondary considerations such as commercial success, long-felt but unsolved needs, failure of others, and unexpected results, if present, can also be considered. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538-39 (Fed. Cir. 1983).

Although these factors can be considered, they do not control the obviousness conclusion. *Newell Cos. v. Kenney Mfg. Co.*, 864 F.2d 757, 768 (Fed. Cir. 1988).

The Kittrell Patent describes a laser endoscope for generating a spectrally resolved spatial image of tissue. Fiber optics positioned within an optically shielded endoscope are used to deliver laser radiation to tissue to be imaged. Radiation returning through the fiber optics from the tissue is spectrally resolved and used to generate an image of tissue that can assist in diagnosis and treatment. (See Kittrell Patent, Abstract).

A generalized spectral system is shown in Figs. 21 and 22 of the Kittrell Patent. As illustrated in Fig. 21, an excitation light 95 is sent from a laser or conventional light source into a selected optical fiber 20. This light passes through a beam splitter 52 or a mirror with a hole 50 (as shown in Fig. 22), and focused onto the input end 40 by a lens 41. The light exits the distal end of the optical fiber 20, passes through the optical shield 12, and impinges on the tissue 34 (of Fig. 4). The fluorescence and scattered light is returned via the same or a different optical fiber 20 to the proximal end 40 of the optical fiber 20. This return light 54 is separated by the beam splitter 52 or by the mirror 50 with hole 51 (see Fig. 22), and enters a spectrum analyzer 60. A diffraction grating 68 of the spectral detector 65 can disperse the return light from a target. The dispersed light is projected onto a multichannel detector 70 which has many detectors. (See *id.*, col. 19, Ins. 20-47). Fig. 13B of the Kittrell Patent illustrates the use of a prism, but without any lens.

The Olinger Patent relates to a needle endoscope includes a hollow needle of about 18-gauge, a lens system within the needle, an image transmitting bundle of flexible fiber-optic rods within the needle, a plurality of illumination transmitting fiber-optic rods within the needle, an operative channel within the needle, and apparatus to shift the image

transmitting bundle with respect to the lens system and needle to provide focus adjustment for focusing the endoscope on objects at various distances from the end of the needle. (See Olinger Patent, Abstract).

The Webb Publication relates to a scanning confocal microscopy system, especially useful for endoscopy with a flexible probe which is connected to the end of an optical fiber (9). The probe has a grating (12) and a lens (14) which delivers a beam of multi-spectral light having spectral components which extend in one dimension across a region of an object and which is moved to scan in another dimension. The reflected confocal spectrum is measured to provide an image of the region. (See Webb Publication, Abstract).

The Baker Patent relates to angioplasty system and method for identification and laser ablation of atherosclerotic plaque at a target site in a blood vessel. Such system and method employ fluorescence analysis for identification of noncalcified plaque and calcium photoemission analysis for identification of calcified plaque. Calcified plaque is identified by time domain analysis of calcium photoemission. A high energy pulsed ultraviolet laser can be used for stimulation of fluorescence and for stimulation of calcium photoemission. The system is capable of distinguishing between calcium photoemission and a defective condition of optical fibers that are used to deliver laser energy to the target site. In an another embodiment of the angioplasty system, calcium photoemission is identified during a nonablative initial portion of the laser ablation pulse. When calcium photoemission is not identified, the laser ablation pulse is terminated during the initial nonablative portion thereof. (See Baker Patent, Abstract).

Independent claim 68, as amended herein above, relates to an apparatus for obtaining information associated with an anatomical structure which comprises, *inter alia*:

a housing;

at least one lens that is different from the housing ...;

an optical waveguide configured to transmit and receive the electro-magnetic radiation and the information from the structure on a macroscopic scale ... ; and

a dispersive arrangement configured to receive ... the electro-magnetic radiation ... ,

wherein the lens and the dispersive arrangement are provided in an optical path between the optical waveguide and the anatomical structure.

Independent claims 89, 113, 125 and 131 have also been amended herein above to recite substantially the same or similar subject matter.

Thus, each of amended independent claims 68, 89, 113, 125 and 131 recites (i) a housing, (ii) a lens separate from the housing, (iii) a dispersive arrangement, and (iv) that **the lens and the dispersive arrangement are provided in an optical path between the optical waveguide and the anatomical structure.** Further, each of amended independent claims 68, 89, 125 and 131 recites that upon being impacted by the radiation from the anatomical structure, the lens forms an image of the anatomical structure.

Applicants respectfully assert that the Kittrell Patent fails to teach, suggest or disclose that the subject matter now recited in amended independent claims 68, 89, 113, 125 and 131, e.g., that **a lens (that is separate from a housing) and a dispersive arrangement are provided in an optical path between an optical waveguide and an anatomical structure.**

The Kittrell Patent shows and describes an optical shield 12 that includes therein one of a lens(es) 221, 222, grating 223, prism 224, mirror 225, or acousto-optic device 229 being provided between the optical fibers 20 and a distal end of the shield 12. (See Kittrell Patent, col. 13, ln. 65 to col. 14, ln. 27; and Figs. 13A-13F). Indeed, the configurations of the Kittrell Patent shown in Figs. 13C and 13D use either the use of the grating 223 or the prism 224 together with the optical shield 12.

As an initial matter, Applicants respectfully assert that it would be improper to equate the optical shield 12 of the Kittrell Patent to the lens(es), as explicitly recited in independent claims 68, 89, 113, 125 and 131. This is because independent claims 68, 89, 113, 125 and 131 have been amended herein above to recite a housing and at least one lens that is *different from the housing*. Further, independent claims 68, 89, 113, 125 and 131 have been amended to recite that “the lens [different from the housing] and the dispersive arrangement are provided in an optical path between the optical waveguide and the anatomical structure.”

Indeed, the prism and the shield 12 shown in Figs. 13C and 13D of the Kittrell Patent (apparently equated by the Examiner to the dispersion arrangement and the lens, respectively, as recited in amended independent claims 68, 89, 113, 125 and 131) is provided in an optical path between the fiber 20 and the sample. There are no other lenses (in addition to the prism shown in Figs. 13C and 13D) described in the Kittrell Patent as being provided in the optical path between the fiber and the sample. In contrast, amended independent claims 68, 89, 113, 125 and 131 explicitly recite that the lens(es) (*which is/are different from the housing*) and the dispersive arrangement are provided in an optical path between the optical waveguide and the anatomical structure. Thus, the Kittrell Patent is

lacking a lens (that is *different from the housing*) and the dispersion arrangement both of which are provided in an optical path between the optical waveguide and the anatomical structure. In contrast, the Kittrell Patent only shows and describes the use of the optical shield 12 (that the Examiner considered the *same as a lens*) and the prism in the optical path between the sample and the fiber(s) 20.

In addition, if lens 21 of the Kittrell Patent is being relied on as being equivalent to the recited lens(es), Applicants respectfully assert that the recitations of amended independent claims 68, 89, 113, 125 and 131 that, e.g., the lens(es) – as well as the dispersive arrangement - is/are provided in an optical path between the waveguide (equated by the Examiner to the fiber 20 of Kittrell) and the anatomical structure, would make such allegation impossible. Indeed, the Kittrell Patent describes that the lens 21 is provided between the spectral analyzed spectral analyzer and the fiber 20. Thus, in Figs. 21 and 22 of the Kittrell Patent, it is the fiber 20 which is provided between the lens 21 and the sample.

Further, Applicants respectfully assert that the radiation provided to the lens 21 from the fiber 20 in the Kittrell Patent is likely a single point thereon, and certainly does not generate any image. This is contrary to the recitation of amended independent claims 68, 89, 125 and 131 that **upon being impacted by the radiation from the anatomical structure, the lens forms an image of the anatomical structure.**

The Olinger Patent, the Webb Publication and/or the Baker Patent do not cure such deficiencies of the Kittrell Patent, and the Examiner does not contend that they do.

Accordingly, Applicants respectfully submit that the Kittrell Patent, taken alone or in combination with the Olinger Patent, the Webb Publication and/or the Baker Patent, does not render obvious the subject matter recited in amended independent claim 68, 89, 113, 125 and 131. The claims which depend from such independent claims are also not taught, suggested or disclosed by the Kittrell Patent, taken alone or in combination with the Olinger Patent, the Webb Publication and/or the Baker Patent for at least the same reasons.

Regarding claim 147, this claim depend from independent claims 74 and independent claim 68, and also recites that **“the optical fiber has an end portion that is provided at a position of an image plane of the at least one section of the structure which is established by the lens.”** In the Answer responding to Applicants' Appeal Brief arguments dated November 29, 2011, the Examiner alleged that because the lens 41 is shown as converging in Fig. 21 of the Kittrell Patent, such illustration would purported make it obvious to those having ordinary skill in the art “that the light is brought to a convergent point at an image plane of the lens in order to direct it into the optical fiber.” (Answer, p. 12, lns. 10-12).

However, nowhere in the Kittrell Patent, and specifically in Fig. 21 thereof is there any illustration, teaching, suggestion or disclosure that the end 40 of the fiber 20 is provided at a position of the image plane of a section of the structure. Indeed, merely because the lens 41 of the Kittrell Patent is converging, that certainly does not mean that the convergence is provided at the position at the image plane where the fiber end 40 is provided. Indeed, the fiber end 40 shown in Fig. 21 of the Kittrell Patent can reside at any other position which would obtain radiation from the lens 41. Such position is not shown,

described or otherwise indicated as being at the position of the image plane of any section of the structure. Clearly, the converge of the lens 41 can be a completely different position and/or plane from a position on the image plane of any section of the structure, as recited in amended claim 147.

Indeed, the PTAB reversed the § 102(b) rejection of this claim in the Decision.

Thus, for at least these reasons, withdrawal of the final rejections of these claims under 35 U.S.C. §§ 102(b) and 103(a) is respectfully requested.

IV. ALLOWABLE SUBJECT MATTER

Applicants gratefully acknowledge the Examiner's indication that claims 142-145 are allowed.

V. NEW CLAIMS 163-165

New claims 163-165 (which depend from amended independent claim 68) have been added above to cover certain exemplary embodiments of Applicants' disclosure. Support for these new claims can be found in the originally-filed specification and drawings. It is respectfully requested that a confirmation of patentability of these claims be provided in the next communication for this application to Applicants' representatives.

VI. CONCLUSION

In light of the foregoing, Applicants respectfully submit that all pending claims 68-82, 84-102, 104-148 and 150-165 are in condition for allowance. Prompt consideration, reconsideration and allowance of the present application are therefore earnestly solicited.

Respectfully submitted,

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